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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,604	04/12/2004	Paul E. Zarembo	279.733US1	2862
21186	7590	01/11/2006	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 1600 TCF TOWER 121 SOUTH EIGHT STREET MINNEAPOLIS, MN 55402			PATEL, JOY	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/822,604	ZAREMBO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joy P. Patel	3766	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 26-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12 and 26-36 is/are rejected.
- 7) ☒ Claim(s) 6 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____                                                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/12/04</u> .                                                             | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities:
  - i. On page 5, paragraph 28, line 12, "neuro stimulation" should be changed to "neurostimulation".
  - ii. On page 8, paragraph 36, line 2, "...electrical conductivity and movable by magnetic flux, for example, a copper ring" should be changed to "...electrical conductivity, which is movable by magnetic flux, such as, a copper ring".

Appropriate correction is required.

### ***Claim Objections***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Misnumbered claims 30-37 have been renumbered respectively to 29-36.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 26, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAuliffe et al. (US 2005/0222660) in view of Wessman et al. (US 6,952,616).
4. In regard to claim 1, McAuliffe discloses, "A lead assembly includes an inner electrode coupled with a conductor, and an outer electrode disposed over the inner electrode, where the outer electrode is coupled with at least a portion of the inner electrode. Insulative material is disposed between a portion of the inner and outer electrodes, for example within a void between the inner and outer electrodes" (Abstract, lines 1-7). However, McAuliffe fails to teach that the conductor is welded to the inner electrode. Wessman, on the other hand, teaches a medical lead for implantation into the patient, which does have the inner conductor welded to the inner electrode. Wessman discloses, "Band electrode 14 is connected to lead body 12 at welding regions 20 by a weld through band electrode 14 to electrically connect the band to conductive pad 24 (considered by the examiner to be the inner electrode). The distal end and proximal end of band electrode 14 are positioned to extend over welding regions 20. Band electrode 14 is connected to the same conductor 22 twice for

exemplary purpose...Welding region 20 provides access to conductor(s) 22 for electrically connecting band electrode 14 to conductor 22...Alternatively, welding region 20 may take a variety of forms and orientations that expose sufficient surface area of conductor 22 to form an electrical connection with a conductive pad (the 2<sup>nd</sup> electrode)...” (Column 4, line 55 – Column 5, line 10). It would have been obvious to one of ordinary skill in the art to modify the device of McAuliffe in view of the teachings of Wessman, in order to create a lead with a secure connection between the conductor and the inner electrode.

5. In regard to claims 3, 29, and 32, McAuliffe discloses, “The method further includes coupling the outer electrode with the inner electrode with an optional coupling projection of the inner electrode, for example by welding the outer electrode to the inner electrode. Another option, is coupling by laser welding” (Paragraph 8, lines 9-13).
6. In regard to claim 30, Wessman discloses, “Conductive pad 24 may be formed by centering a length of wire or other piece of material over welding region and melting the wire or material at a point over the welding region 20. As the material melts, the ends of the wire are drawn into the welding region to form the conductive pad” (Column 5, lines 20-25). The examiner considers this to be a “visible weld” since the wires are drawn into the welding region only when the wire begins to melt, which is something that would have to be inspected visually. Furthermore, in the applicant’s disclosure, the “visible weld” is defined to be one

that "...can be inspected visually before the outer electrode is attached" (Page 6, last line).

7. In regard to claim 26, Wessman discloses, "A weld 26 is typically used to secure the conductive pad 24 (inner electrode) in electrical contact with conductor 22. Alternatively, conductive pad 24 may be secured using an adhesive" (Column 5, lines 25-28).
8. In regard to claim 31, McAuliffe discloses, "Insulative material is disposed between a portion of the inner and outer electrodes, for example within a void between the inner and outer electrodes" (Abstract, lines 4-7).
9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over McAuliffe et al. (US 2005/0222660) in view of Wessman et al. (US 6,952,616) in further view of Spehr et al. (US 6,324,415).
10. In regard to claim 2, McAuliffe in view of Wessman, as discussed above, teaches a lead with an insulative covering, a conductor within the insulative covering, and two electrodes. However, it fails to teach that the inner conductor has a "stepped" portion with a ledge where the conductor is disposed. Spehr, on the other hand, teaches, "The conventional lead and interconnection structure are shown in FIG. 8. The lead 62 includes an inner-coiled cable 63a, and an outer-coiled cable 63b...An inner ring 65 (inner electrode) is disposed around the inner sleeve 64 proximate to an electrode 66 (outer electrode). An outer sleeve 67 surrounds the outer coiled cable 63b and the electrode 66, a metallic connection

tab 68 (considered by the examiner to be the "stepped portion" of the inner electrode) is provided that projects through the outer sleeve 67 and is connected at one end to the electrode 66 and is disposed at the other end between the ring 65 and the outer coiled cable 63b" (Column 8, lines 19-30; See also figure 8). It would have been obvious to modify the device of McAuliffe in view of Wessman, in further view of the teachings of Spehr, in order to have a lead containing an inner electrode with a "stepped portion" as is found in conventional leads.

11. Claims 7, 27, 8, 28, 33, 34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAuliffe et al. (US 2005/0222660) in view of Wessman et al. (US 6,952,616) in further view of Barbec et al. (US 6,253,110).
12. In regard to claims 7 and 27, McAuliffe in view of Wessman, as discussed above, discloses a medical lead with an outer insulative body, a conductor disposed within the insulative body, and an inner electrode coupled to the conductor and an outer electrode, but fails to teach the outer electrode having a treated outer surface. Barbec, on the other hand, teaches an outer electrode having a treated outer surface. Barbec discloses, "The electrode is made by coating a conductive electrode member with a coating of a high surface area coating having micron or sub-micron surface features and after coating, plasma cleaning the electrode member. The electrode is coupled to an insulated conductor of an implantable lead and is employed to stimulate body tissue. The high surface coating may be platinum black, ruthenium oxide, another metal oxide, a metal nitride or the like.

Steroid may be applied to the electrode member after coating" (Abstract, lines 3-12). Barbec further discloses, "One of the most common approaches to reducing post pulse polarization is to provide a high surface area coating having micron or sub-micron size surface features.... or platinum black...a high surface area coating does substantially lower post polarization levels..." (Column 1, lines 19-35). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of McAuliffe in view of Wessman, in further view of Barbec in order to create an implantable lead with electrodes that would minimize post pulse polarization.

13. In regard to claim 8, see rejections for claims 7 and claim 32.
14. In regard to claim 28, see rejection for claim 7. Iridium Oxide (IrOx) is a metal oxide.
15. In regard to claim 33, see rejections for claims 7 and 26
16. In regard to claim 34, see rejections for claims 7 and 31.
17. In regard to claim 36, McAuliffe discloses, "In another option, an outer surface 153 of the one or more coupling projections 152 has a surface to mate with the interior surface of the outer electrode" (Paragraph 28, lines 12-15).
18. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAuliffe et al. (US 2005/0222660) in view of Wessman et al. (US 6,952,616) in further view of Spehr et al. (US 6,324,415).



19. In regard to claims 4 and 5, McAuliffe in view of Wessman, as discussed above, fails to teach that the distal end of the conductor is disposed between the inner and outer electrodes. Spehr, on the other hand, discloses a lead, wherein the distal end of a wire conductor is disposed between the inner and outer electrodes. Spehr discloses, "A multi-filar coil 52 comprises as many insulated-wire coils as there are electrodes on the lead...an end (distal end) 54 of one of the wires is passed through a hole 56 in the tube and laid on an inner ring 58 (considered by the examiner to be the inner electrode)...An outer ring 60 is placed over the inner ring or rings and crimped, capturing the end 54 of the wire between the inner and outer rings. The electrical and mechanical connection between the rings and wire may also be improved by welding or other methods" (Paragraph 39, lines 4-12). It would have been obvious to one of ordinary skill in the art to modify the device of McAuliffe in view of Wessman, in view of the teachings of Spehr, in order to create a medical lead wherein the conductor would be securely connected to the inner and outer electrodes to maintain an electrical connection.
20. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over McAuliffe et al. (US 2005/0222660) in view of Wessman et al. (US 6,952,616) in view of Barbec et al. (US 6,253,110) in further view of Spehr et al. (US 6,324,415).
21. In regard to claim 9, McAuliffe in view of Wessman in further view of Barbec, as discussed above, teaches a medical lead with an insulative covering, a

conductor, an inner electrode, and an outer electrode. However, it fails to teach that the inner and outer electrodes are coupled together by a magnetic swaging process. Spehr, on the other hand, teaches, "After the conductor element 27 is secured to the annular member 58, the annular electrode 21 is positioned and swaged. The swaging serves to reduce the diameter of the annular electrode 21 and to ensure physical contact between the annular electrode 21 and the conductor element 27 and/or the annular member 58.

22. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable McAuliffe et al. (US 2005/0222660) in view of Wessman et al. (US 6,952,616) in view of Barbec et al. (US 6,253,110) in further view of Koblish et al. (US 2002/0087208).
23. In regard to claim 10, McAuliffe in view of Wessman in further view of Barbec, as discussed above, teaches a medical lead with an insulative covering, a conductor, an inner electrode, and an outer electrode. However, it fails to teach that the electrodes are made of a "shape memory" material. Koblish, on the other hand, discloses a catheter wherein, "the electrodes 1714 can be made of the Nitinol material itself" (Paragraph 347, lines 7-8). It is well known in the art that Nitinol is a shape-memory material. It would have been obvious to one of ordinary skill in the art to modify the device of McAuliffe in view of Wessman in view of Barbec in further view of the teachings of Koblish in order to create a lead containing electrodes that follow the shape of the lead as it traverses an internal organ, such as the heart.

24. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over McAuliffe et al. (US 2005/0222660) in view of Wessman et al. (US 6,952,616) in view of Barbec et al. (US 6,253,110) in further view of Schmidt et al. (US 2004/0106959).
25. In regard to claim 11, McAuliffe in view of Wessman in view of Barbec, as discussed above, fails to teach that the inner electrode, the conductor, and the outer electrode are coupled at "substantially the same time". Schmidt, on the other hand, discloses, "An outer ring 60 is placed over the inner ring or rings and crimped, capturing the end 54 of the wire between the inner and outer rings" (Paragraph 39, lines 9-11). This couples the outer electrode, the inner electrode, and the conductor at "substantially the same time". It would have been obvious to one of ordinary skill in the art to modify the device of McAuliffe in view of Wessman in view of Barbec in further view of the teachings of Schmidt, so that the conductor securely connected to the inner and outer electrodes to maintain electrical contact.
26. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over McAuliffe et al. (US 2005/0222660) in view of Wessman et al. (US 6,952,616) in view of Barbec et al. (US 6,253,110) in further view of Black et al. (US 6,981,314).

27. In regard to claim 35, McAuliffe in view of Wessman in view of Barbec, as discussed above, fails to teach the method of "resistance welding" to bind the inner electrode to the outer electrode. Black, on the other hand, discloses, "Transitional element 26 is preferably formed of a conductive material, for example, the same material used to form electrodes 18" (Column 6, lines 29-31). Black further discloses, "...cap electrode 34 is affixed to transitional element 26 using conventional means, for example, resistance welding...." (Column 7, lines 47-50). It would have been obvious to one of ordinary skill in the art to modify the invention of McAuliffe in view of Wessman in view of Barbec in further view of the teachings of black, to use a conventional method, such as resistance welding to connect one conductive material (inner electrode) to another conductive material (outer electrode).

#### ***Allowable Subject Matter***

28. Claims 6 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joy P. Patel whose telephone number is 571-272-5556. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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